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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,752	05/22/2001	Katsushi Tokunaga	2000-1639A	1603

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EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/725,752	TOKUNAGA ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ *Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).*

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *16* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ELECTION/RESTRICTION

1. The response filed November 1, 2002, paper no. 15, has been entered. However, upon further consideration, the prior Election/Restriction of paper no. 14 is withdrawn, and restriction and election are required as set forth below. See also the Interview Summary of paper no. 16, a copy of which is enclosed herewith.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to reagents "having a specific affinity for" nucleic acids, classified in class 536, subclasses 23.5 and 24.31.

II. Claims 6-9, drawn to reagents "having a specific affinity for" proteins, classified in class 530, subclass 387.1.

III. Claims 10-11 and 14, drawn to diagnostic methods in which nucleic acids are detected, classified in class 435, subclass 6.

IV. Claims 12-13 and 15, drawn to diagnostic methods in which proteins are detected, classified in class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and in functional properties. Invention I is drawn to nucleic acids, which are composed of nucleotides linked by phosphodiester bonds, while Invention II is drawn to antibodies, which are composed of amino acids linked by peptide bonds and having a particular tertiary structure. The reagents of Invention I function in, e.g.,

hybridization assays, while the antibodies of Invention II function in, e.g., methods of protein purification. Accordingly, Inventions I and II are patentably distinct from one another.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Invention I may be used in a materially distinct process, such as methods of synthesizing protein.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Invention I are not disclosed as capable of use in the methods of Invention IV and are employed in methods having different functions and effects, such as methods of nucleic acid hybridization.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Invention II are not disclosed as capable of use in the methods of Invention III and are employed

in methods having different functions and effects, such as methods of protein purification.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Invention II may be used in materially different processes, such as methods of protein purification.

Inventions III and IV are patentably distinct methods that require the use of different reagents and different process steps to achieve the detection of different types of target molecules. Invention III requires the use of, e.g., nucleic acid probes in a step of analyzing gene expression, while Invention IV requires the use of, e.g., antibodies in a step of analyzing protein expression. Accordingly, Inventions III and IV are patentably distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-IV require different searches that are no co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following **patentably distinct species** of the claimed invention:

a) Invention I encompasses 60 possible combinations of reagents, each of which is a distinct species. Specifically, the Invention embraces the 15 possible combinations of the 4 reagents of claim 1, as well as these 15 combinations in combination with a cytochrome oxidase subunit I reagent (15 combinations), a cytochrome b reagent (15 combinations), or both a cytochrome oxidase subunit I reagent and a cytochrome b reagent (15 combinations)(see claim 3).

b) Invention II encompasses 60 possible combinations of reagents, each of which is a distinct species. Specifically, the Invention embraces the 15 possible combinations of the 4 reagents of claim 6, as well as these 15 combinations in combination with a cytochrome oxidase subunit I reagent (15 combinations), a cytochrome b reagent (15 combinations), or both a cytochrome oxidase subunit I reagent and a cytochrome b reagent (15 combinations)(see claim 8).

c) Invention III encompasses 60 possible combinations of genes, each of which is a distinct species. Specifically, the Invention embraces the 15 possible combinations of the 4 genes of claim 10, as well as these 15 combinations in combination with a cytochrome oxidase subunit I gene (15 combinations), a cytochrome b gene (15 combinations), or both a cytochrome oxidase subunit I gene and a cytochrome b gene (15 combinations)(see claim 11).

d) Invention IV encompasses 60 possible combinations of proteins, each of which is a distinct species. Specifically, the Invention embraces the 15

possible combinations of the 4 proteins of claim 12, as well as these 15 combinations in combination with a cytochrome oxidase subunit I protein (15 combinations), a cytochrome b protein (15 combinations), or both a cytochrome oxidase subunit I protein and a cytochrome b protein (15 combinations)(see claim 13).

In addition to electing one of Groups I-IV, Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species** of the elected Invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 6, 10, and 12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
January 12, 2003